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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,568	08/03/2001	Catherine Shoemaker	1960-00100	6318

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EXAMINER

CARTER, MONICA SMITH

ART UNIT	PAPER NUMBER
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3722

DATE MAILED: 02/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/853,568

Applicant(s)

SHOEMAKER, CATHERINE

Examiner

Monica S. Carter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, there is an inconsistency between the language in the preamble and a certain portion or portions of the body of the claim, thereby making the scope of the claim indefinite and unclear. Applicant is required to clarify what subject matter the claim is intended to be drawn to, i.e., either the subcombination of an iconic label alone or the combination of a housing, a cover, and an iconic label, and that the language of the claim be amended to be consistent with this intent. For the purpose of prosecution, the Examiner is considering the claims as combination claims.

Claims 2-6 depend from claim 1 and, therefore, are also rejected accordingly.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayfield (5,261,702).

Mayfield discloses the claimed invention including a housing inherently having an open end (end which the medicine is to be entered) and an external surface (outside surface of the medication container), the housing is configured to retain dosages of medicine; a cover removably secured to the open end which separates the medicine held within from the outside environment; and an iconic label (22) disposed on the cover to graphically describe the medicine held therein (see figs. 4 and 5 and col. 7, lines 39-41). Regarding claim 2, Mayfield discloses an iconic label disposed on the external surface (see figs. 4 and 5 and col. 7, lines 42-46).

Regarding claim 3, Mayfield discloses the iconic label comprising a representation (having a particular shape) that communicates to a patient application for which the medicine is to be used by the patient.

Regarding claim 12, Mayfield discloses the markers being a graphical colored symbol (col. 7, lines 31-38).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayfield, as used above.

Regarding claims 7-10, Mayfield discloses the method of applying the label (22) to the exterior of the receptacle (col. 7, lines 36-38).

Regarding claim 11, the label has first and second sides, the first side having an adhering surface (col. 7, lines 31-33) and the second side having an external printable media (22).

Mayfield discloses the claimed invention except for the specific arrangement and/or content of indicia (printed matter) set forth in claims 4-9 and 10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide any type of graphic representation on the cover, since it would only depend on

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the intended use of the assembly and the desired information to be displayed. Further, it has been held that when the claimed printed matter is not functionally related to the substrate it will not distinguish the invention from the prior art in terms of patentability. In re Gulack 217 USPQ 401, (CAFC 1983). The fact that the content of the printed matter placed on the substrate may render the device more convenient by providing an individual with a specific type of iconic label does not alter the functional relationship. Mere support by the substrate for the printed matter is not the kind of functional relationship necessary for patentability. Thus, there is no novel and unobvious functional relationship between the printed matter and the substrate which is required for patentability.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rollman (5,011,032) discloses a patient dosage regimen compliance bottle cap, Palti (5,700,998) discloses drug coding, Glynn (5,774,865) discloses a patient compliance and monitoring system, Luoma (6,032,609) discloses a dosage indicator medicine container and Song (6,227,371) discloses a medical container and system.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica S. Carter whose telephone number is (703) 305-

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0305. The examiner can normally be reached on Monday-Thursday (8:00 AM - 5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrea L. Wellington can be reached on (703) 308-2159. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

  
Monica S. Carter  
February 15, 2002